

Appendix 2

Combined Studies: Cethromycin Baseline MICs for Each Pathogen by both Clinical and Bacteriological Outcomes in MITT Population

Organism	MIC (µg/mL)	Cethromycin		Clarithromycin	
		Bacteriological Eradication (n/N)	Clinical Cure (n/N)	Bacteriological Eradication (n/N)	Clinical Cure (n/N)
<i>Streptococcus pneumoniae</i>	0.004	26/31 (84%) 1/1 (100%)	25/31 (81%) 1/1 (100%)	28/34 (82%) 1/1 (100%)	25/34 (73%) 0/1 (0%)
	0.008	7/8 (88%)	7/8 (88%)	11/12 (92%)	11/12 (92%)
	0.015	13/16 (81%)	12/16 (75%)	10/13 (77%)	8/13 (62%)
	0.03	5/5 (100%)	5/5 (100%)	2/2 (100%)	2/2 (100%)
	0.06			2/3 (67%)	2/3 (67%)
	0.12	0/1 (0%)	0/1 (0%)		
	0.25			1/1 (100%)	1/1 (100%)
	missing			1/2 (50%)	1/2 (50%)
	Penicillin-Sensitive	26/31 (84%) 1/1 (100%)	25/31 (81%) 1/1 (100%)	27/32 (84%) 1/1 (100%)	24/32 (75%) 0/1 (0%)
	0.004	7/8 (88%)	7/8 (88%)	11/12 (92%)	11/12 (92%)
	0.008	13/16 (81%)	12/16 (75%)	10/13 (77%)	8/13 (62%)
	0.015	5/5 (100%)	5/5 (100%)	2/2 (100%)	2/2 (100%)
	0.03			2/3 (67%)	2/3 (67%)
	0.06				
	0.12	0/1 (0%)	0/1 (0%)		
	0.25			1/1 (100%)	1/1 (100%)
	Penicillin-intermediate	0	0	0	0
	Penicillin-resistant	0	0	0	0
<i>Haemophilus Influenzae</i>	0.002	56/68 (82%) 1/1 (100%)	56/68 (82%) 1/1 (100%)	43/47 (91%)	43/47 (91%)
	0.008			0/1 (0%)	0/1 (0%)
	0.5	2/2 (100%)	2/2 (100%)	2/2 (100%)	2/2 (100%)
	1	7/9 (78%)	7/9 (78%)	5/5 (100%)	5/5 (100%)
	2	23/28 (82%)	24/28 (86%)	20/23 (87%)	20/23 (87%)
	4	16/18 (89%)	16/18 (89%)	10/10 (100%)	10/10 (100%)
	8	5/5 (100%)	4/5 (80%)	5/5 (100%)	5/5 (100%)
	16			1/1 (100%)	1/1 (100%)
	32	1/1 (100%)	1/1 (100%)		
	missing	1/4 (25%)	1/4 (25%)		
	beta-lactamase negative	45/52 (87%)	45/52 (87%)	36/40 (90%)	36/40 (90%)
	0.002	1/1 (100%)	1/1 (100%)		
	0.008			0/1 (0%)	0/1 (0%)
	0.5	2/2 (100%)	2/2 (100%)	2/2 (100%)	2/2 (100%)
	1	6/8 (75%)	6/8 (75%)	4/4 (100%)	4/4 (100%)
	2	20/23 (87%)	21/23 (91%)	17/20 (85%)	17/20 (85%)
	4	11/12 (92%)	11/12 (92%)	10/10 (100%)	10/10 (100%)
	8	4/4 (100%)	3/4 (75%)	2/2 (100%)	2/2 (100%)
	16			1/1 (100%)	1/1 (100%)
	missing	1/2 (50%)	1/2 (50%)		

beta-lactamase positive		11/16 (69%)	11/16 (69%)	7/7 (100%)	7/7 (100%)
	1	1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)
	2	3/5 (60%)	3/5 (60%)	3/3 (100%)	3/3 (100%)
	4	5/6 (83%)	5/6 (83%)		
	8	1/1 (100%)	1/1 (100%)	3/3 (100%)	3/3 (100%)
	32	1/1 (100%)	1/1 (100%)		
	missing	0/2 (0%)	0/2 (0%)		
<i>Moraxella</i> <i>Catarrhalis</i>		5/7 (71%)	5/7 (71%)	10/10 (100%)	9/10 (90%)
	0.06	3/3 (100%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
	0.12	1/2 (50%)	1/2 (50%)	7/7 (100%)	6/7 (86%)
	0.25	1/2 (50%)	1/2 (50%)		
	beta-lactamase negative	0	0	1/1 (100%)	1/1 (100%)
	0.12			1/1 (100%)	1/1 (100%)
	beta- lactamase positive	5/7 (71%)	5/7 (71%)	9/9 (100%)	8/9 (89%)
	0.06	3/3 (100%)	3/3 (100%)	3/3 (100%)	3/3 (100%)
	0.12	1/2 (50%)	1/2 (50%)	6/6 (100%)	5/6 (83%)
	0.25	1/2 (50%)	1/2 (50%)		
<i>Staphylococcus</i> <i>Aureus</i>		17/23 (74%)	18/23 (78%)	21/25 (84%)	22/25 (88%)
	0.03	1/1 (100%)	1/1 (100%)	2/2 (100%)	2/2 (100%)
	0.06	15/20 (75%)	16/20 (80%)	18/21 (86%)	19/21 (90%)
	0.12	1/1 (100%)	1/1 (100%)	1/2 (50%)	1/2 (50%)
	>32	0/1 (0%)	0/1 (0%)		
	methicillin- susceptible	16/22 (73%)	17/22 (77%)	20/24 (83%)	21/24 (88%)
	0.03	1/1 (100%)	1/1 (100%)	2/2 (100%)	2/2 (100%)
	0.06	15/20 (75%)	16/20 (80%)	17/20 (85%)	18/20 (90%)
	>32	0/1 (0%)	0/1 (0%)	1/2 (50%)	1/2 (50%)
	methicillin- resistant	1/1 (100%)	1/1 (100%)	1/1 (100%)	1/1 (100%)
	0.06			1/1 (100%)	1/1 (100%)
	0.12	1/1 (100%)	1/1 (100%)		

Source: Table 5, Microbiology Request, this submission.